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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/666,490 | 09/19/2003 | Jian Li | CEN0312NP | 8016 |

27777 7590 04/05/2006

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| EXAMINER | |
|---|---|
| WOODWARD, CHERIE MICHELLE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/666,490 | LI ET AL. | |
| | Examiner | Art Unit | |
| | Cherie M. Woodward | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Formal Matters*

1. Applicants' election without traverse of claims 8-11 in the reply to the Restriction/Election filed on 30 January 2006 is acknowledged. Claims 1-7 and 12-19 have been cancelled by Applicants. Claims 8-11 are under examination.

### *Information Disclosure Statement*

2. The information disclosure statement (IDS) submitted on 12 August 2005 has been considered. A signed copy is attached hereto.

The reference to the PCT Search Report has been lined through. However, the references contained in the search report are listed on page 1 of the IDS form, individually, and have thus, been considered. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

### *Specification*

3. The disclosure is objected to because of the following informalities:

a. There are a series of blank lines on page 5, lines 14-16.

b. An extra "0" is listed in the phrase "95%-1000%" on p. 14, line 13.

c. TNF-_, page 30, line 35.

d. There is no web-based reference affiliated with "copewithcytokines.com" (see specification, p. 31, line 5). If the reference is intended to be directed to www.copewithcytokines.de, then the phrase should be corrected to recite the correct web-based reference.

Appropriate correction is required.

4. The use of the trademarks, such as NASBA (page 7, line 28), NEUPOGEN (p. 17, line 9, p. 28, line 5, p. 31), EPOETIN ALPHA (p. 17, line 9, p. 28, line 4, p. 31), LEUKINE (p. 17, line 9, p. 28, line 5, p. 31), numerous trade names on page 22, lines 23-31, including HUMATROPEN (p. 22, line 31), multiple inhalers and nebulizers listed on page 35, have been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which Applicants may become aware in the specification.

6. The attempt to incorporate subject matter into this application by reference to GenBank Accession numbers and laboratory names of proteins is ineffective because protein and nucleic acid sequences that are an essential part of the invention must be disclosed by sequence. As such, the incorporation by reference to GenBank Accession Numbers and references to proteins by their laboratory names are not in compliance with 37 CFR 1.57. Applicant may overcome the rejection by amending the specification in accordance with 37 CFR 1.57(g). However, no new matter may be introduced.

7. The disclosure is objected to under 37 CFR 1.821(d) because a SEQ ID NO is required for any disclosed peptide with four or more amino acids. No SEQ ID NOs have been provided for the amino acid sequences in excess of four amino acids referenced in the disclosure (see i.e. p. 45).

***Claim Rejections - 35 USC § 112, Second Paragraph***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the claim, as written, whether the "further" is part of the recited methodor whether what follows is a new method. A remedial suggestion to the claim language would be "A dendritic cell preparation produced by the method of claim 8 further comprising contacting...."

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lardon et al., (Immunology 1997 Aug;91(4):553-9).

The claims recite a preparation of dendritic cells having at least two cell surface markers selected from the group consisting of CD1a, HLA-DR, and CD86, produced by contacting hematopoietic stem or progenitor cells with IL-18. A dendritic cell preparation according to claim 8, produced further by contacting the hematopoietic stem or progenitor cells with a molecule selected from the group consisting of flt-3-ligand, GM-CSF-IL-4, TNF-a, IL-3, c-kit ligand, and fusions of GM-CSF and IL-13. An antigen expressing dendritic cell population produced by the recited process, wherein step a of the process further comprises contacting the hematopoietic stem cell or progenitor cells with a molecule selected from the group consisting of GM-CSF, IL-4, TNF-a, IL-3, c-kit ligand, and fusions of GM-CSF and IL-3.

Lardon et al., teach the generation of dendritic cells from bone marrow progenitors. Phenotypic analysis of dendritic cells with cell surface markers HLA-DR, CD1a, and CD86 are taught at p. 555. The claimed preparations of dendritic cells and antigen-expressing dendritic cells are well known in the art

(see, i.e. Lardon et al., *supra*). "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

12. Claims 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Zitvogel et al., US Patent 6,849,452 (1 February 2005, priority to 2 March 1999) (hereinafter the '452 patent).

The claims recite a preparation of dendritic cells having at least two cell surface markers selected from the group consisting of CD1a, HLA-DR, and CD86, produced by contacting hematopoietic stem or progenitor cells with IL-18. A dendritic cell preparation according to claim 8, produced further by contacting the hematopoietic stem or progenitor cells with a molecule selected from the group consisting of flt-3-ligand, GM-CSF-IL-4, TNF-a, IL-3, c-kit ligand, and fusions of GM-CSF and IL-13. An antigen expressing dendritic cell population produced by the recited process, wherein step a of the process further comprises contacting the hematopoietic stem cell or progenitor cells with a molecule selected from the group consisting of GM-CSF, IL-4, TNF-a, IL-3, c-kit ligand, and fusions of GM-CSF and IL-3.

The '452 patent teaches a preparation of dendritic cells, compositions containing them, and uses thereof (column 2, lines 52-55). The '452 patent also teaches a the use of dendritic cells to prepare a composition intended to activate natural killer (NK) cells *in vivo* (column 2, lines 40-43), including culturing the cells in the presence of IL-18 (column 1, lines 61-63). The bone-marrow derived dendritic cells (column 7, lines 30-31) expressing HLA-DR, CD40, CD80, CD86, CD83, and CD1a are taught at column 6, lines 16-18. The dendritic cells treated with GM-CSF and Flt3L are taught at column 12, lines 9-25. IL-4 is taught at column 4, lines 30-31, and GM-CSF plus IL-13 is taught at column 14, lines 9 and 27. Antigen-stimulated dendritic cells and numerous methods of producing them are taught at column 14, lines 60-67 to column 15, lines 1-67 to column 16, lines 1-18. Specifically, antigen-pulsing is taught at column 15, lines 19-31 and transfecting dendritic cells with a gene encoding an antigenic-specific peptide is taught at column 16, lines 1-18.

**NO CLAIM IS ALLOWED.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMW

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